UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Pesticide Programs

Antimicrobials Division (AD)

October 01, 2012.

DP BARCODE: 404721.

MRID#s : 48885200, 48885201 & 48885202.

SUBJECT: **ORD-X209.**

REG. NO.: 75340-A

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
024409	14215-52-2	Copper Ethanolamine Complex
011103	12008-41-2	Disodium Octaborate Tetrahydrate.

TEST LAB: Osmose, Inc.

SUBMITTER: Osmose Inc.

GUIDELINE: OPPTS Guidelines 830 Groups “A & B”.

ORGANIZATION: AD\PSB\CTT

REVIEWER: Salvador Rodriguez.

APPROVED BY: Karen P. Hicks

APPROVED DATE: 10/10/12.

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MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 75340-A
Product Name: ORD-X209.
DP Barcode: 404721

CODE: (A540)

DATE DUE: 12/07/12.

FROM: Salvador Rodriguez, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Campbell-McFarlane PM#34/Jaclyn Carl.
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Osmose Inc.

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	**% by wt.**
Copper ethanolamine complex……	….5.84
Disodium Octaborate Tetrahydrate……	….5.00

BACKGROUND:

The Registrant, Osmose Railroad Services, Inc., has submitted the OPPTS 830 Groups "A & B" studies, and Confidential Statements of Formula (CSFs) for the basic and alternate # 2 formulations, to support the registration for the disinfectant non-integrated, non-food end-use product **ORD-X209.** The product chemistry reviewer has reviewed the following documents:

- Confidential Statements of Formula, pin punched 06/20/12, for the basic and alternate formulations.
- Label, pin punched 07/13/12.
- Studies Titled: "ORD-X209". OPPTS Guidelines Groups "A & B". Product Chemistry Data. MRID#'s: 48885201 & 48885202.
- Transmittal letter, pin punched 07/13/12.
- Statement of Good Laboratory Practice, dated 07/11/12.

FINDINGS:

1. The CSF, dated 06/20/12, for basic and alternate # 2 formulations are revised.

2. All the certified limits meet the EPA standard certified limits.

3. The CSFs and the label have the same nominal.

4. The OPPTS Guidelines Group A product chemistry data requirements applicable to end-use products have been met. MRID#: 48885201

5. The OPPTS Guidelines Group "B" product chemistry data requirements applicable for end-use products have been met with the exception of the OPPTS Guidelines: 830.6317 "Storage Stability" & 830.6320 "Corrosion Characteristics" MRID#: 48885202.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the CSF for 75506-RL for the basic formulation and the OPPTS 830 Guidelines groups "A & B" product chemistry requirements for non-integrated, non-food end-use products to be acceptable, with the exception of the OPPTS Guidelines: 830.6317 "Storage Stability" and 830.6320 "Corrosion Characteristics. These studies will be submitted upon completion.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [X]
]

c. Physical state of product: *Liquid.*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Copper ethanolamine complex ……	5.84	5.55	6.13
Disodium Octaborate Tetrahydrate……	5.00	4.75	5.25

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [ ] No [X] Not applicable [ ]
- Have all impurities of ≥ 0.1% in the product been identified?
Yes [X] No [ ] Not applicable [ ]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X]
No []

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No []

Note: The Storage Stability study is in progress and will be submitted upon Completion.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	48885201
830.1600 Description of Materials	A	48885201
830.1620 Production Process[2]	NR	
830.1650 Formulation Process[3]	A	48885201
830.1670 Formation of Impurities[4]	NR	
830.1700 Preliminary Analysis[5]	NR	
830.1750 Certified Limits[6]	A	48885201
830.1800 Enforcement Analytical Method[7]	A	48885201
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for manufacturing-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NR	Dark blue	48885202
830.6303 Physical State	A	Liquid	48885202
830.6304 Odor	NR	Mild	48885202
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Observations of appearance and temperature change were made upon mixing, after one minute, and after 24 hours. No significant changes have been observed.	48885202
830.6315 Flammability/ Flame Extension	A	This product is water-based.	48885202
830.6316 Explodability	A	The product is not considered to present a danger of explosion under the test conditions.	
830.6317 Storage Stability	W	This study is currently in progress and will be submitted upon completion.	48885201
830.6319 Miscibility[1]	A	The product is not miscible in non-polar organic compounds.	48885201
830.6320 Corrosion Characteristics	W	This study is currently in progress and will be submitted upon completion.	48885201
830.6321 Dielectric Breakdown Voltage	A	This product is not to be used around electrical equipment.	48885201
830.7000 pH[2]	A	The pH of the product was reported to be 8.6 (1% solution in water).	48885202
830.7050 UV/Visible Absorption	NR	*[Not required for end-use products.]*	
830.7100 Viscosity	A	1.52 centipoises at 26° C 1.15 centipoises at 38° C	48885202

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7200 Melting Point/Melting Range	NA	The product is liquid	48885202
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	1.080 g/cc (9.01 lb/gal) at 26º C; 1.075 at 38º C.	48885202
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water